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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,134	07/11/2003	Gerold Schuler	106985-2 KGB	4429
27384 7590 10/15/2009 NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022			EXAMINER JUEDES, AMY E	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 10/15/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,134	SCHULER ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 11, 29, 30, 35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 29, 30 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/24/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment and remarks, filed 7/16/09, are acknowledged.
Claims 37-38 have been cancelled.
Claim 9 has been amended.
Claims 9, 11, 29-30 and 35-36 are pending.
2. Claim 36 stands withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
Claims 9, 11, 29-30, and 35 are being acted upon.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 11, 29-30, and 35 stand rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US Patent Application Publication 2002/0090357, as evidenced by Fujimaki et al., 2008.

As set forth previously, The '357 publication teaches a method of making IL-10 producing Tr1 regulatory T cells comprising culturing naïve CD45RA+CD4+ human T cells with anti-CD3 and anti-CD28 antibodies in the presence of immunosuppressive agents ex vivo (see page 2, 4, and 8 in particular). Furthermore, as evidenced by Fujimaki et al., naïve CD45RA+ human CD4 + T cells comprise both CD25+ cells and CD25- cells. Thus, culturing total naïve CD4+ T cells, as taught by the '357 publication, inherently involves "co-culturing" both CD4+CD25+ T cells and CD4+CD25- T cells, as recited in the instant claims. Additionally, said T cells are "activated" by the culture with anti-CD3 and anti-CD28. Additionally, the '357 publication teaches stimulating with plate bound

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anti-CD3 and soluble anti-CD28 (see pages 8-9, in particular). Furthermore, the '357 publication teaches that regulatory T cells have the capacity to inhibit T cell proliferation in vitro (see page 1 in particular).

Applicant's arguments filed 7/16/09 have been fully considered, but they are not persuasive.

Applicant argues that the '357 publication does not teach an activation stimulus "consisting of" anti-CD3 and anti-CD28, as recited in the amended claims, since the '357 publication teaches stimulating the naive T cells with a stimulatory signal and Vitamin D3 and dexamethasone. Applicant notes that the present claims require only a stimulatory signal (i.e. anti-CD3/anti-CD28), but exclude other elements (such as vitamin D3 and dexamethasone) due to the "consisting of" language.

As an initial matter, it is noted that the '357 publication teaches that vitamin D3 and dexamethasone are immunosuppressive agents (see page 2), and are not considered to be an "activation stimulus" as recited in the instant claims. Furthermore, it is noted that the instant claims are drawn to a method for producing regulatory T cells which "comprises" activating CD4+CD25+ T cells with an activation stimulus consisting of plate bound anti-CD3 and soluble anti-CD28. The use of "consisting of" in the body of the claims does not limit the open-ended "comprising" language of the claims (see MPEP 2111.03). Thus, the instant claims are open to additional unrecited steps or elements. The '357 publication teaches a method of producing regulatory T cells comprising contacting unactivated CD4+CD25+ T cells with an immunosuppressive agent and an activation stimulus consisting of plate-bound anti-CD3 and soluble anti-CD28, which reads on the instant claims.

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 7am to 3:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes

Patent Examiner

Technology Center 1600

/Amy E. Juedes/

Patent Examiner, Art Unit 1644